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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  574313-3359	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  on _____  Signature _____  Typed or printed name _____	Application Number  10/544,281	Filed  8/3/2005	
	First Named Inventor  Quaranta		
	Art Unit  1616	Examiner  Sabiha Qazi	
	Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.    This request is being filed with a notice of appeal.    The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.    I am the  <input type="checkbox"/> applicant/inventor.  <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)  <input type="checkbox"/> attorney or agent of record. Registration number _____  <input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>48,104</u>		
		<u>Howard C. Lee</u> _____ Signature Howard C. Lee _____ Typed or printed name  (212) 588-0800 _____ Telephone number  8 November 2007 _____ Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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## REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

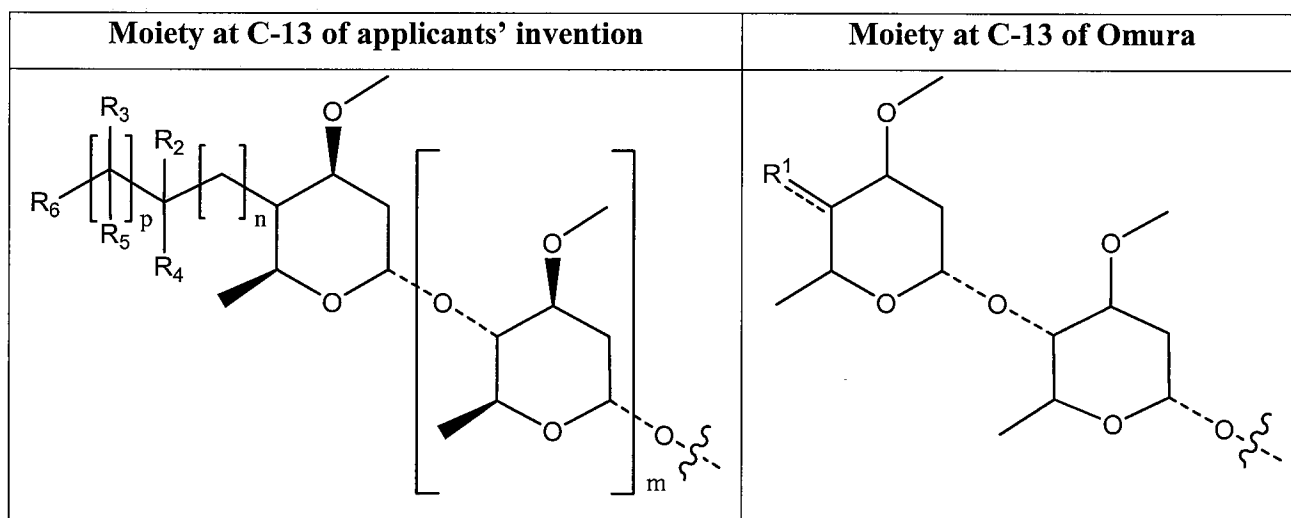
### I. Status of claims

Claims 1-4 and 7-20 are pending in this application. There are no amendments after final to be considered.

### II. There is a clear factual deficiency in the obviousness rejection based on Omura of applicants' claims which results in all claim limitations not being taught

A prima facie case of obviousness is not established if all claim limitations have not been taught or suggested by the cited reference. *See* MPEP 2143.03. For the pending claims, Omura does not teach or suggest all of the applicants' claim limitations. Moreover, this requirement applies to all pending claims not just the pending independent claims.

Both the applicants claims and Omura are directed toward avermectin-type compounds. However, Omura is directed toward a different type of avermectin derivative than that of the applicants', specifically the moieties attached to the hydroxy group at the C-13 position (see formula (I) in col. 1 of Omura) of the avermectin core structure are different - these moieties are presented below:



#### **A. There is no “embracing” of applicants' claimed invention by Omura**

The Omura rejection in the Office Action of 7 August 2007 began by stating:

“The reference teaches avermectin derivatives having high antiparasitic activity, which embraces Applicant's claimed invention. See entire document especially formula (I) and lines 1-67 in col. 1, lines 1-58 in column 2, preparation, Tables 1-8 in column 37-45 and claims

Instant claims differ from the reference in that they are of different generic scope.”

This assessment of Omura is in error as the scope of Omura is completely outside that of the applicants’ claimed invention.

A general reference to Omura’s compounds can be found on col. 1, line 34 through col. 2, line 58. One clear distinction between the Omura and the applicants’ claimed invention is that in Omura most of disclosure is directed for the situations where the bond between the saccharide and R<sup>1</sup> is a **double bond** (“...the line --- between R<sup>1</sup> and a carbon atom at the 4” position represents a double bond;” - see col. 1, lines 63-64, col 2, lines 24-25 and 48-49).

The link between the saccharide and the carbon atom in the applicants’ claimed invention is a **single bond**.

Omura does have a description for the situations where the link between R<sup>1</sup> and the saccharide is a single bond, but this description is extremely limited, i.e. encompasses only carboxymethyl (HOOC-CH<sub>2</sub>-) and cyanomethyl (NC-CH<sub>2</sub>-) - see col. 2, lines 40-42 (“...or when the line --- between R<sup>1</sup> and a carbon atom at the 4” position represents a single bond, R<sup>1</sup> may represent a carboxymethyl group or a cyanomethyl group.”).

However, both of these moieties are excluded from the scope of the applicants’ compounds by the proviso which is at the end of the applicants’ claim 1 (“...with the proviso, that the group R<sub>6</sub>-[C(R<sub>3</sub>)(R<sub>5</sub>)]<sub>p</sub>-C(R<sub>2</sub>)(R<sub>4</sub>)-[CH<sub>2</sub>]<sub>n</sub>-, which is attached to the ε-position of the compound of the formula (1), **is not NC-CH<sub>2</sub>- or HOOC-CH<sub>2</sub>-** when m is 1 and the bond between atoms 22 and 23 is a single bond.” (emphasis added)).

Therefore, there is no overlap between Omura and the applicants’ claimed invention.

Claims 2-4 and 7-20 are all ultimately dependent upon claim 1 and therefore, this factual deficiency applies to these claims as well.

#### **B. Monosaccharide vs. Disaccharide (Claims 10, 13, 15 and 17)**

In addition to the factual deficiency described above, claims 10, 13, 15 and 17 have a further factual deficiency, specifically recited that m = 0, i.e. the moiety at C-13 is a **monosaccharide** whereas in Omura, the moiety at C-13 is a **disaccharide**.

**C. Alkyl chain is longer than a single CH<sub>2</sub> group (Claims 11-13, 17, 18 and 20)**

In addition to the factual deficiency described in A. above, the alkyl chains in claims 11-13, 17, 18 and 20 are longer than the single CH<sub>2</sub> referred to in Omura. Claims 12 and 13 require at least a two carbon chain and claims 11, 17, 18 and 20 require at least a three carbon chain. Moreover, claims 17, 18 and 20 describe at least a (R<sub>6</sub>)(R<sub>5</sub>)C=C(R<sub>4</sub>)-CH<sub>2</sub>- moiety, i.e. includes an alkene group.

**D. Omura does not teach a comparable hydroxy moiety (Claim 19)**

In addition to the factual deficiency described in A. above, applicants claim 19 describes compounds where the 4'' substitution is either HO-CH<sub>2</sub>- or HO-CH<sub>2</sub>-CH<sub>2</sub>- which is not described by Omura.

For any of the above reasons, the rejection over Omura is in error and should be withdrawn.

Respectfully submitted,  
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